Dear Teri Nguyen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's
requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eleni Whatley
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure
Device Name

Indigo Aspiration System

Indications for Use (Describe)

INDIGO Aspiration Catheters and Separators:
As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

INDIGO Aspiration Tubing:
As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump:
The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D)
- Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
1 **510(k) Summary**  
(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra, Inc. is providing the summary of Substantial Equivalence for the Indigo® Aspiration System.

1.1 **Sponsor/Applicant Name and Address**
Penumbra, Inc.  
One Penumbra Place  
Alameda, CA 94502 USA

1.2 **Sponsor Contact Information**
Teri Nguyen  
Regulatory Affairs Specialist II  
Phone: (510) 995-2012  
FAX: (510) 217-6414  
Email: tnguyen2@penumbrainc.com

1.3 **Date of Preparation of 510(k) Summary**
December 19, 2019

1.4 **Device Trade or Proprietary Name**
Indigo® Aspiration System

1.5 **Device Classification**
Regulatory Class: II  
Classification Panel: Cardiovascular  
Classification Name: Catheter, Embolectomy  
Regulation Number: 21 CFR §870.5150  
Product Code: QEW

1.6 **Predicate and Reference Devices**

<table>
<thead>
<tr>
<th>510(k) Number/Clearance Date</th>
<th>Name of Device</th>
<th>Name of Manufacture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Predicate Device</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| K142870 cleared on May 26, 2015    | Penumbra Embolectomy Aspiration System (INDIGO Aspiration System) | Penumbra, Inc.  
One Penumbra Place  
Alameda, CA 94502 USA |
| **Reference Device**               |                                                          |                                                   |
| K180939 cleared on May 03, 2018    | INDIGO Aspiration System                                 | Penumbra, Inc.  
One Penumbra Place  
Alameda, CA 94502 USA |
| K180466 cleared on May 19, 2018    | FlowTriever Retrieval/Aspiration System                  | Inari Medical, Inc.  
9272 Jeronimo Road  
Suite 124  
Irvine, CA 92618 USA |
### 1.7 Predicate Comparison

<table>
<thead>
<tr>
<th>System Name</th>
<th>Predicate Device</th>
<th>Reference Device</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) No.</td>
<td>K142870</td>
<td>K180939</td>
<td>K192833</td>
</tr>
<tr>
<td>Classification</td>
<td>Class II, DXE</td>
<td>Class II, QEW</td>
<td></td>
</tr>
<tr>
<td>Indication for Use</td>
<td>The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. Not for use in the coronaries or the neurovasculature.</td>
<td>INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.</td>
<td>INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.</td>
</tr>
<tr>
<td></td>
<td>INDIGO Aspiration Tubing: As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.</td>
<td>The FlowTriever Retrieval/Aspiration System consists of the FlowTriever Catheter, Aspiration Guide Catheter, and Retraction Aspirator. The FlowTriever Retrieval/Aspiration System is indicated for: • The non-surgical removal of emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The FlowTriever Retrieval/Aspiration System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.</td>
<td>INDIGO Aspiration Tubing: As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.</td>
</tr>
</tbody>
</table>
### Device Description

The INDIGO® Aspiration System is comprised of several devices:

- INDIGO Aspiration Catheter
- Penumbra Aspiration Pump
- INDIGO Aspiration Pump Canister
- INDIGO Aspiration Tubing
- INDIGO Separator™

The INDIGO Aspiration System is designed to remove thrombus from the vasculature using mechanical aspiration. The INDIGO Aspiration Catheter targets aspiration from the pump directly to the thrombus. The INDIGO Separator may be used to clear the lumen of the INDIGO Aspiration Catheter should it become blocked with thrombus. The INDIGO Aspiration Catheter is introduced through a guide catheter or vascular sheath and into the peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The INDIGO Aspiration Catheter is used with the Penumbra Aspiration Pump to aspirate thrombus from an occluded vessel. As needed, an INDIGO Separator may be deployed from the INDIGO Aspiration Catheter to assist with thrombus removal. The INDIGO Separator is advanced and retracted through the INDIGO Aspiration Catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the INDIGO Aspiration Catheter tip. The devices are visible under fluoroscopy. For the aspiration source, the INDIGO Aspiration Catheter is used in conjunction with the Penumbra Aspiration Pump, which is connected using the INDIGO Aspiration Tubing and the INDIGO Aspiration Pump Canister. The INDIGO Aspiration Catheter may be

<table>
<thead>
<tr>
<th>Packaging, Materials &amp; Configurations</th>
<th>Predicate Device</th>
<th>Subject Device¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Commonly utilized for interventional devices</td>
<td>SAME</td>
</tr>
<tr>
<td>Aspiration Source</td>
<td>Penumbra Aspiration Pump</td>
<td>SAME</td>
</tr>
<tr>
<td>Sterilization</td>
<td>EO</td>
<td>SAME</td>
</tr>
<tr>
<td>Shelf-Life</td>
<td>36 Months</td>
<td>SAME</td>
</tr>
<tr>
<td>Use</td>
<td>Single use, disposable</td>
<td>SAME</td>
</tr>
</tbody>
</table>

¹The Indigo System Aspiration Catheters, Separators, Tubing and Penumbra Aspiration Pumps are unchanged and remain identical to those currently cleared in Section 1.6.
provided with a steam shaping mandrel, rotating hemostasis valve, and introducer. The INDIGO Separator may be provided with an introducer and torque device.

1.9 Indications for Use

INDIGO Aspiration Catheters and Separators:

As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.

INDIGO Aspiration Tubing:

As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump:

The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

1.10 Summary of Non-Clinical Data

The subject and predicate Indigo System devices are identical. Therefore, previous device performance data regarding substantial equivalence described below remain unchanged.

1.10.1 Biocompatibility

The subject and predicate Indigo System sterile devices are identical. There are no changes to the previously provided biocompatibility data of the Indigo System sterile device materials, which were reviewed and cleared under the premarket notifications listed in 1.6. No additional biocompatibility testing is required or was performed for the Indigo System sterile devices.

The subject and predicate Indigo System devices are categorized and tested as a limited exposure (≤24 hours), externally communicating device with circulating blood contact in
accordance with EN ISO 10993-1, USP standards, and FDA Good Laboratory Practices (GLP). Biocompatibility test results demonstrate biological safety per BS EN ISO 10993 and USP requirements.

1.10.2 Design Verification (Bench-top Testing)

The subject and predicate Indigo System devices are identical. There are no changes to the previously provided bench-top data of the devices, which were reviewed and cleared under the premarket notifications listed in 1.6. No additional bench-top testing is required or was performed for these devices.

1.10.3 Design Validation – Animal Study

The subject and predicate Indigo System devices are identical. There are no changes to the previously provided animal testing data of the devices, which were reviewed and cleared under the premarket notifications listed in 1.6. No additional animal testing is required or was performed for these devices.

1.10.4 Performance Data – Clinical

1.10.4.1 Introduction

The Penumbra EXTRACT-PE trial was a prospective, multicenter, single arm trial to determine the safety and efficacy of the Indigo Aspiration System for mechanical thrombectomy in subjects with acute pulmonary embolism (PE).

1.10.4.2 Study Design

The Penumbra EXTRACT-PE trial was a prospective, multicenter, single arm trial. The trial enrolled 119 subjects at 22 centers in the U.S. An independent imaging core lab and a clinical events committee (CEC) reviewed safety endpoints data.

1.10.4.3 Methods

The study procedure was initiated in 119 subjects and completed in 118 subjects; one subject had the procedure aborted prior to aspiration. Conscious sedation was
used in 97.5% of subjects and 78.2% had a right femoral access site. The median procedure time was 66 min; IQR [46.0, 94.0]. The median time from the first Indigo device insertion to the last Indigo device removal was 37 minutes; IQR [23.5, 60.0]. The median ICU stay was 1.0 day [1.0, 2.0].

The treatment included the following pulmonary embolism locations:

<table>
<thead>
<tr>
<th>Treatment Location</th>
<th>All Subjects (N=119)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main PA with Unilateral</td>
<td>0.8% (1/119)</td>
</tr>
<tr>
<td>Main PA with Bilateral</td>
<td>23.5% (28/119)</td>
</tr>
<tr>
<td>Unilateral Only</td>
<td>5.9% (7/119)</td>
</tr>
<tr>
<td>Bilateral Only</td>
<td>69.7% (83/119)</td>
</tr>
</tbody>
</table>

1.10.4.4 Study Results

There were 119 subjects that were enrolled and included in the Intent-To-Treat (ITT) analysis population. The Modified ITT (mITT) population was a subset of the ITT population and was the primary population for all efficacy parameters. The mITT population excluded subjects who received adjunctive treatments or thrombolytics intra-procedure through 48 hours post-procedure for the purpose of reducing clot burden in the pulmonary artery. There were 110 subjects in the mITT population. Safety endpoints are evaluated based on ITT population.

There were 110 patients who completed the study 30 day follow-up, 3 patients died, 1 withdrew from the study, and 5 were lost to follow-up.

The primary efficacy endpoint was the reduction in RV/LV ratio from baseline to 48 hours assessed by CTA and evaluated by independent core laboratory. The lower limit of the 95% confidence interval (CI) of the change in RV/LV ratio at 48 hours was >0.20. The primary efficacy endpoint was met with absolute reduction in RV/LV ratio of 0.42±0.25 (95%CI 0.37, 0.46), representing a 26.9% reduction (p<0.0001). The primary safety endpoint was major adverse events, a composite of device-related death, major bleeding, and device-related SAEs (defined as clinical deterioration, pulmonary vascular injury, and cardiac Injury) within 48 hours. The safety hypothesis stated that the 48-hour rate of major
adverse events would not equal 40%. The primary safety endpoint was met and the rate was 1.7% (95% CI 0.0%, 4.0%), p<0.0001).

1.10.4.5 Conclusion

The EXTRACT-PE trial demonstrated that the Indigo Aspiration System showed substantially equivalent safety and effectiveness outcomes for acute PE. The primary efficacy and safety endpoints were met.

1.10.5 Shelf Life

The subject and predicate Indigo System are identical. There are no changes to the previously provided shelf-life data for the devices, which were reviewed and cleared under premarket notifications listed in 1.6. No additional stability testing is required or was performed for the Indigo System sterile devices.

1.10.6 Sterilization

The subject and predicate Indigo System sterile devices are identical and utilize the same Ethylene Oxide (EO) gas exposure sterilization method in accordance with BS EN ISO 11135. There are no changes to the previously provided sterilization data of the devices, which were reviewed and cleared under the premarket notifications listed in 1.6. No additional sterilization testing is required or was performed for these devices.

1.10.7 Packaging

The packaging materials and process of the subject and predicate Indigo System are identical. There are no changes to the previously provided packaging material listing or the packaging process for these devices, which were reviewed and cleared under the premarket notifications listed in 1.6. No additional packaging testing is required or was performed.

1.11 Summary of Substantial Equivalence

Compared to the predicate device, the expanded indication of the Indigo Aspiration System does not change the intended use. Based on the leveraged results of pre-clinical testing and
the EXTRACT-PE Clinical Study, the data supports that the Indigo Aspiration System is substantially equivalent to the predicate device.